

IV. REMARKS

A. Status of the Application

Claims 1, 6-17, 22, 27-36 and 40-43 are pending herein. Claims 1, 22 and 40 have been amended. It is respectfully submitted that claims 1, 6-17, 22, 27-36 and 40-43, as amended, are supported by the specification as filed and are in condition for allowance. Favorable consideration and allowance of claims 1, 6-17, 22, 27-36 and 40-43 in view of the foregoing amendments and the following remarks are respectfully requested.

B. Status of Foreign Countepart Applications

Applicants refer to the Information Disclosure Statement filed concurrently with this Response and note that patents corresponding to this application have been granted in Australia, European Patent Office (Germany, Spain, France, Switzerland/Liechtenstein, United Kingdom, Ireland, Italy), Hong Kong, Mexico, New Zealand, Singapore and South Africa. Applicants are pursuing patents in other jurisdictions and will update the foregoing list from time to time as additional patents are granted.

C. Rejection Under 35 U.S.C. § 112

Claims 1, 6-17, 22, 27-36 and 40-43 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to provide support or antecedent basis for the language “wherein said composition is preservative-free and said saccharides are bioavailable as monosaccharides” in claims 1, 22 and 40. Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Claims 1, 22 and 40 have been amended to delete the objectionable text noted above. Claims 1, 22 and 40 have also been amended to specify that the claimed compositions include predigested forms of the specified saccharides. In this regard, the Examiner’s attention is respectfully directed to page 8, lines 19-23 of the present application which discloses that according to one embodiment, the compositions include predigested forms of the saccharides. Reference is also made to page 12, lines 5-7 which discloses that the terms “carbohydrate” and “saccharide” are used interchangeably in the present application.

Filed herewith are Declarations Under 37 C.F.R. §1.132 of Robert K. Murray, Stephen Boyd and Thomas H. Gardiner, each of whom is an expert in various fields pertaining to biochemistry, carbohydrates and pharmacology. The facts set forth in the Declarations of Drs. Murray, Boyd and Gardiner establish that it is the predigestion of the saccharides that makes the saccharides bioavailable as monosaccharides. As noted in the present application, predigestion of the saccharides may be accomplished by one or more well known techniques such as:

“1) physical digestion such as shearing or treatment with ultrasound, 2) chemical digestion such as enzymatic digestion, and acid or base hydrolysis, and 3) biological digestion with microbes such as bacteria, fungi or molds.”

Also, Example 4 (page 18, line 19 to page 19, line 6) discloses that the saccharides can be hydrolyzed into monosaccharides by treatment with acid.

In view of the foregoing, Applicants submit that the rejection of claims 1, 6-17, 22, 27-36 and 40-43 under 35 U.S.C. §112, first paragraph has been overcome and it is therefore requested that it be withdrawn. Applicants also submit that claims 1, 22 and 40, as amended, are in full compliance with all aspects of 35 U.S.C. §112. Finally, when read in light of the specification, Applicants submit that the amendments of claims 1, 22 and 40 do not narrow the claims with regard to the claimed dietary supplement compositions.

D. Rejections Under 35 U.S.C. § 102(b)

Claims 1, 6, 16 and 22 stand rejected under 35 U.S.C. §102(b) over U.S. Patent No. 4,871,557 to Linscott (hereafter referred to as “Linscott ‘557”). As provided in MPEP § 2131, “[t]o anticipate a claim, the reference must teach every element of the claim . . .”. Therefore, Linscott ‘557 must disclose all of the elements of claims 1, 6, 16 and 22 to sustain this rejection. Applicants respectfully traverse this rejection on the following grounds.

Linscott ‘557 discloses a granola bar with supplemental fiber such as apple pectin, gum arabic, gum ghatti and guar gum. Linscott ‘557, however, does not disclose or suggest that the apple pectin, gum arabic, gum ghatti or guar gum are predigested.

Reference is again made to the Declarations Under 37 C.F.R. §1.132 of Drs. Murray, Boyd and Gardiner. The facts set forth in the Declarations of Drs. Murray, Boyd and Gardiner

establish that unless the fibers disclosed in Linscott '557 are treated in some manner such as by predigestion, the constituent saccharides of such fibers will not be bioavailable as monosaccharides.

The Murray, Boyd and Gardiner Declarations also establish that while the fibers disclosed in Linscott '557 may include various constituent saccharides, the saccharides are not bioavailable as monosaccharides.

The Examiner points to Examples 5 and 6 of the application as somehow providing evidence that the compositions disclosed by Linscott '557 inherently read upon bioavailable monosaccharides. As noted in MPEP §2112, "[T]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Also, as noted by the Patent Office Board of Appeals:

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis in original).

It is respectfully submitted that the Examiner has not provided a basis in fact and/or technical reasoning to support the determination that the compositions disclosed by Linscott '557 necessarily include bioavailable monosaccharides. In addition, it is respectfully submitted that it is improper to use Applicant's specification to establish what is allegedly inherently disclosed by an applied reference.

Moreover, regardless of what is disclosed in Examples 5 and 6 of Applicant's specification, the patentability of claims 1, 6, 16 and 22 is to be determined on the basis of the subject matter covered by these claims. Claims 1, 6, 16 and 22 are directed to dietary supplement compositions that include nutritionally effective amounts of certain saccharides in which the compositions include predigested forms of the saccharides. Whether or not Applicant's specification includes one or more examples that disclose a composition that is also disclosed by a reference is irrelevant to the patentability of Applicant's claims unless such claims are limited to the same subject matter as disclosed in such examples.

Also, contrary to what is stated in the Office action and as noted in the Declarations of Drs. Murray, Boyd and Gardiner, the present application expressly discloses the predigestion of

carbohydrates whereby the constituent saccharides of such carbohydrates are made bioavailable as monosaccharides. See page 8, lines 19-23 of the present application.

It is important to recognize that prior to Applicant's invention and as noted in the Declarations of Drs. Murray, Boyd and Gardiner, there was no recognition in the art that there was any nutritional value in making such saccharides bioavailable as monosaccharides. Indeed, the prevailing view at the time and to a large extent today, is that sugars are a source of energy only and there is largely no recognition that sugars are important substances for glycoprotein production. Indeed, as of the filing date of the present application, there was no recognition that there was any nutritional value to providing a dietary supplement composition that makes monosaccharides bioavailable because the prevailing view was that to the extent sugar was a dietary necessity, the abundance of glucose in the human diet satisfied this dietary necessity. This view has since been refuted by many learned papers which have been disclosed during the prosecution of this application.

Prior to Applicant's invention, there was no motivation in the art to make saccharides bioavailable as monosaccharides. Instead, the prevailing view was that making such saccharides bioavailable as monosaccharides was to be avoided. Linscott '577 is simply devoid of any disclosure or suggestion of a composition in which such saccharides are predigested so as to make them bioavailable as monosaccharides.

According to MPEP § 2131, to anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim". Claims 1 and 22 recite, in part, dietary supplement compositions comprising nutritionally effective amounts of at least six saccharides in which the compositions include predigested forms of the saccharides. As noted above, Linscott '557 fails to disclose or suggest a composition which includes nutritionally effective amounts of saccharides in which the compositions include predigested forms of the saccharides as required by MPEP § 2131. Therefore, claims 1 and 22 as well as claims 6 and 16 which depend therefrom are allowable over Linscott '557. For the foregoing reasons, it is requested that the rejection of claims 1, 6, 16 and 22 over Linscott '557 be withdrawn.

Claims 1 and 22 stand rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,021,560 to Montreuil et al. (hereafter Montreuil '560). As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim . . .". Therefore, Montreuil '560 must

disclose all of the elements of claims 1 and 22 to sustain this rejection. Applicants respectfully traverse this rejection on the following grounds.

Montreuil '560 discloses a glycoprotein extracted from Keyhole Limpet hemocyanin in which the glucidic fraction represents 5 to 5.25% of the glycoprotein molecule and the glucidic fraction includes mannose, galactose, fucose, glucose, xylose, N-acetylglucosamine and N-acetylgalactosamine.

Montreuil '560, however, similar to Linscott '557, does not disclose or suggest treating the glycoprotein in some manner such as predigestion to make the constituent saccharides of the glycoprotein bioavailable as monosaccharides. As noted in the Declarations Under 37 C.F.R. §1.132 of Drs. Murray, Boyd and Gardiner, Montreuil '560 discloses an antigenic epitope that requires that the entire glycoprotein structure be intact to provide antigenicity. It is contrary to the disclosure of Montreuil '560 that the antigenic epitope could be used as a source of saccharides for nutritional supplementation. Any suggestion otherwise is merely the result of an impermissible hindsight reconstruction of Applicant's claimed subject matter.

According to MPEP § 2131, to anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim". Claims 1 and 22 recite, in part, dietary supplement compositions comprising nutritionally effective amounts of at least six saccharides in which the compositions includes predigested forms of the saccharides. Montreuil '560 fails to disclose or suggest these elements as required by MPEP § 2131. Therefore, claims 1 and 22 are allowable over Montreuil '560. For the foregoing reasons it is requested that the rejection of claims 1 and 22 over Montreuil '560 be withdrawn.

Claim 40 stands rejected under 35 U.S.C. §102(b) over Citkowitz, Developmental Biology 27, 494-503 (1977) (hereafter Citkowitz) or Ortega U.S. Patent No. 3,947,601 (hereafter Ortega '601). As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim . . .". Therefore, Citkowitz or Ortega '601 must disclose all of the elements of the claim to sustain these rejections. Applicants respectfully traverse these rejections on the following grounds.

According to Citkowitz an analysis of the hyaline layer of sea urchin embryos reveals that the hyaline layer is 2-3% carbohydrate and that the carbohydrate portion includes: fucose,

xylose, mannose, galactose, glucose, N-acetylglucosamine, N-acetylgalactosamine and N-acetylneuraminic acid.

Ortega '601 discloses a food for fish and invertebrates which is compatible with a closed circuit salt water aquarium that includes broken sea urchin eggs.

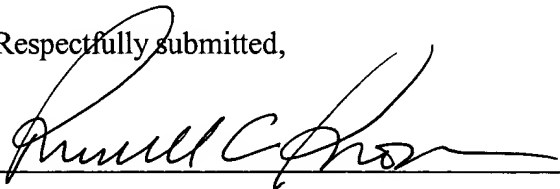
However, similar to Linscott '557, and as discussed in the Declarations Under 37 C.F.R. §1.132 of Drs. Murray, Boyd and Gardiner, neither Citkowitz nor Ortega '601 disclose or suggest treating the hyaline layer or the sea urchin eggs in some manner such as predigestion to make the constituent saccharides bioavailable as monosaccharides.

According to MPEP § 2131, to anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim". Claim 40 recites, in part, a dietary supplement composition comprising nutritionally effective amounts of predigested forms of eight specified saccharides. Both Citkowitz and Ortega '601 fail to disclose or suggest this element as required by MPEP § 2131. Therefore, claim 40 is allowable over either or both Citkowitz and Ortega '601. For the foregoing reasons it is requested that the rejection of claim 40 over Citkowitz or Ortega '601 be withdrawn.

For all of the foregoing reason, it is respectfully submitted that claims 1, 6-17, 22, 27-36 and 40-43 are in condition for allowance. Favorable reconsideration and allowance of claims 1, 6-17, 22, 27-36 and 40-43 are respectfully requested.

Respectfully submitted,

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